510(k) Summary

Contact: Justin Eggleton
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Date Prepared: November 18, 2013

Device Trade Name: Tiger® OCT System

Manufacturer: CoreLink, LLC
10805 Sunset Office Drive, Suite 300
St. Louis, MO 63127

Common Name: OCT System

Classification: 21 CFR §888.3050; Spinal interlaminal fixation orthosis

Class: II

Product Code: KWP, MNH, MNI.

Indications For Use:
Tiger® Occipital-Cervical-Thoracic Spinal Fixation System is intended to promote fusion of the cervical spine and the occipito-cervico-thoracic junction (occiput-T3). The system is intended to be used in skeletally mature patients as an adjunct to fusion using autograft and allograft for the following conditions: degenerative disc disease (DDD): defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies; spondylolisthesis; spinal stenosis; fracture/dislocation; atlanto/axial fracture with instability; occipitocervical dislocation; revision of previous cervical spine surgery; and tumor.

The occipital bone screws are limited to occipital fixation only. Hook components are indicated for use from C1-C7. The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3). They are not intended to be placed in the cervical spine.

The Tiger® Occipital-Cervical-Thoracic Spinal Fixation System can be connected to the Tiger® Spine System using the side by side and end to end rod to rod connectors.

Device Description:
The CoreLink Tiger® OCT System consists of occipital plates, occipital bone screws, cervical hooks, upper thoracic pedicle screws, rods in both titanium and cobalt chrome.

transverse connectors, and other various connectors. These components are manufactured from Ti-6Al-4V ELI in accordance with ASTM F136.

Predicate Device(s):
The Tiger® OCT System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. These devices include the Pioneer Surgical Streamline OCT System (K121725), DePuy Spine Mountaineer OCT Spinal System (K110353), and Synthes Synapse OCT System (K091689).

Performance Standards:
Testing performed on this device indicates that the Tiger® OCT System is substantially equivalent to predicate devices. ASTM F2706 performance standards were adhered to and all applicable requirements were met. This testing included static compression bending, static torsion, dynamic torsion, and dynamic compression bending.

Conclusion:
The Tiger® OCT System is substantially equivalent to predicate devices with respect to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Corelink, LLC
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Justin Eggleton
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

November 25, 2013

Re: K132504
Trade/Device Name: TIGER® OCT System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNH, MNI
Dated: November 18, 2013
Received: November 20, 2013

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K132504

510(k) Number (if known): _____

Device Name: CoreLink Tiger® OCT System

Tiger® Occipital-Cervical-Thoracic Spinal Fixation System is intended to promote fusion of the cervical spine and the occipito-cervico-thoracic junction (occiput-T3). The system is intended to be used in skeletally mature patients as an adjunct to fusion using autograft and allograft for the following conditions: degenerative disc disease (DDD): defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies; spondylolisthesis; spinal stenosis; fracture/dislocation; atlanto/axial fracture with instability; occipitocervical dislocation; revision of previous cervical spine surgery; and tumor.

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132504